

## *Fertility & Sterility*

### Abstracts

Vol. 78, No. 3, Suppl. 1, September 2002, pages S108-S109

Wednesday, October 16, 2002  
2:30 P.M.

**0-285**

**The anthrax vaccine does not affect semen parameters, embryo quality, or pregnancy outcome in couples with a vaccinated male military service member.** William H. Catherino, Andrew Levi, Mark Leondires, James H. Segars, Ruben Alvero, Jeffery McKeeby. Preb, NICHD, NIH, Bethesda, MD; Combined Fed Program in Reproductive Endocrinology at WRAMC, NNMC, USUHS, and NIH, Washington, DC; Univ of Colorado Health Science Ctr, Aurora, CO.

**Objective:** The United States military has used the anthrax vaccine since 1998 in an effort to prevent infection should anthrax be used as a biological weapon. Although there is no proven association between anthrax vaccination and reproductive sequelae, concerns have been raised given the broad exposure in predominantly reproductive-age soldiers. The impact of anthrax vaccination on reproductive outcome has not been previously assessed in men. The Assisted Reproductive Technologies program based at Walter Reed Army Medical Center in Washington, D.C. has performed ART cycles exclusively on military service members. This population base provides a unique opportunity to assess the association between anthrax vaccination and the quality of gametes, embryos, and pregnancy outcomes.

**Design:** Cohort retrospective analysis.

**Materials/Methods:** From February 2000 to February 2002, all participating males were routinely asked if they had received any portion of the anthrax series. One hundred and twenty have responded affirmatively, 424 have responded negatively, and responses were not available for 235 men. We compared demographic parameters including age, clomid citrate challenge test results, and diagnosis between couples receiving and not receiving the vaccination. Semen parameters are shown in Table 1 and reproductive outcomes are shown in Table 2. Students T-test and  $X^2$  were used to identify significance as indicated, with a  $p < 0.05$  determining significance. Sample size was determined by the interval of study, and not by power analysis.

**Results:** Please see Tables 1 and 2. There was no statistical difference between age, diagnosis, clomid citrate challenge test results (data not shown).

Table 1. Semen parameters and use of micromanipulation.

	Anthrax Vaccine	No Vaccine
Concentration (million/mL)	70.1	70.8
Motility (%)	69.6	70.5
Morphology		
< 4%	2.5	6.9
5-14%	74.4	56.7
> 14%	23.1	36.3
ICSI required (%)	21.7	35.6

Table 2. Embryo quality and reproductive outcome.

	Anthrax Vaccine	No Vaccine
Fertilization (%)	83.5	80.6
High Grade Transferred (%)	58.1	61.5
Blastocysts Transferred (%)	29.0	24.0
Chemical Pregnancy (%)	8.1	6.0
Clinical Pregnancy (%)	52.4	47.7

Conclusions: Based on the differences observed in clinical pregnancy rates between men who received and did not receive the anthrax vaccine, ad hoc power analysis indicated that a sample size of 928,708 patients would be required to detect a difference between these two groups with 80% power. Exposure to the anthrax vaccine by males who were undergoing IVF did not alter semen parameters, fertilization rate, embryo quality, or pregnancy rates.

*Supported by: Pediatric and Reproductive Endocrine Branch, National Institute of Child Health and Human Development, and the National Institutes of Health.*